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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/843,914	04/30/2001	Bozidar Ferek-Petric	P-8191	9906

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EXAMINER

OROPEZA, FRANCES P

ART UNIT PAPER NUMBER

3762

DATE MAILED: 12/30/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/843,914

Applicant(s)

FEREK-PETRIC, BOZIDAR

Examiner

Frances P. Oropeza

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/25/03 (Amendment).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. The Applicant's submission filed on 11/25/03 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1 and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Applicant amended claims 1 and 20 to include "monitoring a blood pressure sensor upon detecting the heart rate greater than the heart rate threshold value to detect a substantial drop in blood pressure; invoking a first" NID upon detecting the heart rate greater than the heart rate threshold value "if a substantial drop in blood pressure is not detected; invoking a second" NID threshold "that is lower than the first NID threshold upon detecting a

substantial drop in blood pressure” and “the tachycardia detection being a detection of a hemodynamically stable tachycardia if the first NID threshold is invoked and a tachycardia detection being a detection of a hemodynamically unstable tachycardia if the second NID threshold is invoked”. The Examiner has reviewed the method disclosed in the specification, page 4, line 21 through page 5, line 7, and has reviewed the discussion of the measurement of the blood pressure, page 23, lines 17-26, and is unable to find the limitations noted above in parentheses. It appears the limitations in parentheses are new matter and new matter may not be introduced at this point in the prosecution. Appropriate correction is required.

4. Claim 1 and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Examiner is unable to find the apparatus and systems to support the invoking of a first and a second NID threshold based on a lack of a substantial drop in blood pressure or based on a substantial drop in blood pressure respectively.

Claim Rejections - 35 USC § 103

5. Claims 1 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alt (US 5458622) in view of Bardy et al. (US 5257621).

Alt discloses an apparatus and method, substantially as claimed, to provide multiple threshold and therapy levels to successfully treat tachycardia (figure 4; col. 9 @ 38-47; col. 9 @ 60 – col. 10 @ 19). The heart rate threshold increases and decreases based on the non-ECG sensor output (hemodynamic parameter / physiologically-sensed condition / hemodynamic measurement). When the heart rate (counted interval(s)) is equal to or greater than a threshold or less than the threshold, a second threshold is adjusted and therapy is provided, as needed, to treat the tachycardia (col. 11 @ 18-49; col. 12 @ 5-28; col. 13 @ 7-11; col. 14 @ 44-51 and 56-61; col. 15 @ 40-51). The intervals are consecutive, as non-consecutive intervals indicate dysrhythmia (col. 5 @ 50-57; col. 6 @ 64 – col. 7 @ 5).

Resetting the threshold can comprises increasing or decreasing the threshold, based on the blood pressure feedback or based on a predetermined relationship between the physiologically-sensed condition. Inherently, the threshold is reduced with a reduction in blood pressure (col. 5 @ 45-49; col. 11 @ 35-44).

The hemodynamic sensor, the activity sensor (34), can also be an indirect sensor such as a sensor of blood pressure or a blood flow rate sensor (col. 3 @ 12-26; col. 7 @ 64 – col. 8 @ 3; col. 9 @ 47-52).

As to identification and treatment of hemodynamically stable and unstable tachycardia, Alt discloses the use of two independent sensors, an ECG sensor and a complementary non-ECG sensor (blood pressure sensor) used in combination to provide a clear indication of an individual's condition so proper tiered therapy can be provided given stability or lack of stability of the blood pressure at a given level (col. 3 @ 12-26; col. 3 @ 63 – col. 4 @ 19;

col. 10 @ 35-46; col. 11 @ 40-49; col. 12 @ 5-21). US 5342404 to Alt, incorporated by reference (col. 3 @ 13-19), elaborates on therapy control based on hemodynamic function as represented by blood pressure (col. 6 @ 21-42).

As discussed in the previous two paragraphs, Alt discloses the claimed invention except for: using controller circuitry to initiate an adjustable number of intervals detected (NID) threshold, resetting the adjustable NID threshold based on at least a first measurement of a value (hemodynamic parameter / physiologically-sensed condition / a predetermined relationship / a hemodynamic measurement / a blood pressure measurement), and detecting tachycardia if the consecutive number of intervals satisfies / is equal to or greater than / the adjustable NID threshold.

Bardy et al. disclose an apparatus for detection of, discrimination between and treatment of tachycardia and fibrillation and teach the following elements:

- use of control circuitry to identify a single value that detects tachyarrhythmias,
- use of subsequent values to appropriately adjust the threshold level and therapy, wherein the threshold is adjusted by varying the number of intervals for detection of tachycardia in each tachycardia rate zone, the threshold being a potentially unique number of intervals for each tachycardia rate zone, and
- use of measurements associated with the current heart rate intervals for adjusting the number of intervals required to for detection of tachycardia, the measurements read to be a hemodynamic parameter /physiologically-sensed condition / hemodynamic

measurement, , hence teaching the invoking of different NIDs based on the blood pressure .

Modification of the PCD as taught by Alt with the elements above is motivated because use of less stringent criteria for tachycardia detection as the tachycardia event progresses enables the patient to receive more rapid effective treatment (col. 17 @ 22-36; col. 18 @ 1-43; col. 19 @ 4-7).

The Applicant arguments filed 11/25/03 have been fully considered but they are not convincing.

In response to the Applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which the Applicant relies (i.e., the NIDs being adjustable based on rate/ measurements associated with rate) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Claims Objections

6. Claim 20 is objected to because of apparent grammatical issues. In claim 20, lines 8-10 it is suggested "sensing" be amended to --sense--, "comparing" be amended to --compare-- and "monitoring" be amended to --monitor-- to be consistent with "circuitry operable to" in line 7.

Specification

7. The amendment filed 11/25/03 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: In claims 1 and 20, “monitoring a blood pressure sensor upon detecting the heart rate greater than the heart rate threshold value to detect a substantial drop in blood pressure; invoking a first” NID upon detecting the heart rate greater than the heart rate threshold value “if a substantial drop in blood pressure is not detected; invoking a second” NID threshold “that is lower than the first NID threshold upon detecting a substantial drop in blood pressure” and “the tachycardia detection being a detection of a hemodynamically stable tachycardia if the first NID threshold is invoked and a tachycardia detection being a detection of a hemodynamically unstable tachycardia if the second NID threshold is invoked”.

Applicant is required to cancel the new matter in the reply to this Office Action.

Statutory Basis

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza, telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

Application/Control Number: 09/843,914
Art Unit: 3762

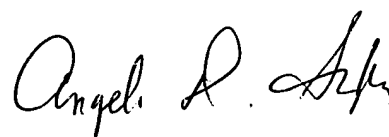
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If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 306-4520 for regular communication and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist, telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

JRO
12/24/03



ANGELA D. SYKES
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